

**MECHANICAL VARIABLE RATE FLOW CONTROL
FOR A CONSTANT PRESSURE IV DELIVERY SYSTEM**

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of United States Provisional Patent Application No. 60/396,610, filed on 07/19/02, the contents of which are incorporated herein by reference thereto.

The present invention relates generally to improvements concerned with two popular methods to control flow with a fixed rate of flow. One is with capillary tubes and the other uses restrictive flow tubing sets. The improvements address the problem of how to provide a wide range of fixed flows accurately using the available technology.

Example of the Prior Art

U.S. Patent 5,318,515 for "Intravenous Flow Regulator Device And Associated Method" issued to Wilk discloses the use of fixed, different flow passages with flow rates such as .25cc/hr, 50cc/hr, 100cc/hr and 200cc/hr that are opened and closed by manually operated switches to achieve a range of flow rates. A drawback in Wilk however is that an operating mode of opening and closing switches is undesirable not only because it is implemented manually, but also because it cannot be readily correlated to ascending and descending flow rates except by reference to written instructions, and the correlation noted is undesirable in making flow rate adjustments.

Broadly, it is an object of the present invention to overcome the foregoing and other shortcomings of the prior art.

More particularly, it is an object to obtain the switch operation which provides the flow control in a rotational rather than a finger manipulation, and to thereby obviate human error, all as will be better understood as the description proceeds.

The description of the invention which follows, together with the accompanying drawings should not be construed as limiting the invention to the example shown and described, because those skilled in the art to which this invention appertains will be able to devise other forms thereof within the ambit of the appended claims.

Fig. 1 is an exploded perspective view of the unassembled components of a variable rate flow control for a constant pressure IV delivery system according to the present invention; and

Fig. 2 is an isolated view of a knob component of Fig. 1, illustrating further structural details.

The illustrated preferred embodiment demonstrates how four capillaries (1) functioning as flow restrictions are connected in a binary fashion to permit 15 different flow rates in one assembly, as illustrated in Fig. 1. It is to be understood that each capillary (1) has a binary numerical value, i.e., 1, 2, 4, 8 and can be allowed to flow by pressing on the pistons (7) which open normally-closed spring operated valves (not shown) housed in the valve block (9). The inlet 11 from an IV bag (not shown) is on the left in fluid communication with the common manifold inlet (5) for the four capillaries (1).

The knob (2) selects any flow, in this example, from 1ml/hr to 15 ml/hr or off, i.e., no valves open for flow, or a total of 15 positions. That is, if the four tubes (1) in this example are made to flow with the first (encountered proceeding from the left) tube at 1ml/hr, the second at 2ml/hr, the third at 4ml/hr and the fourth at 8ml/hr, one can set flow rates from

1ml/hr, the first capillary tube by itself to, for example 10ml/hr, combining 2ml/hr with 8ml/hr, all the way up to 15 ml/hr, i.e., $1+2+4+8=15$. With X signifying an open valve and 0 closed, the 15 positions are: 1=X000; 2=0X00; 3=XX00; 4=00X0; 5=X0X0; 6=0XX0; 7=XXX0; 8=000X; 9=X00X; 10=0X0X; 11=XX0X; 12=00XX; 13-X0XX; 14=0XXX; 15=XXXX.

By turning the knob (2) each flow setting can be accurately selected and using the bosses(10), correlated by position to open the normally closed valves or not by camming contact against the pistons (7) or avoiding such contact, the former bosses (10) identified as exemplary by the reference letter X and the latter bosses (10) by the reference letter 0, are provided on the underside of the knob (2), the exemplary binary position illustrated in Fig. 2 being position 1 or X000. In this manner the rotational operating mode of knob (2) depresses the appropriate piston(s) (10) to generate the selected flow automatically, thereby obviating manual operation of on-off switches as in the noted Wilks patent.

In a preferred embodiment the knob (2) will have a pointer that will align with specific flow rates from 0-15ml/hr in 1ml/hr increments. Also, the components of Fig. 1 in assembled relation will be housed in a thin clamshell of cover (4) and base (3) maintaining a convenient flat profile, making it easy to inconspicuously attach to a patient's arm. A locking mechanism optionally can be added to the device (4), (3) to prevent patient tampering when used in ambulatory treatments.

In use, the system can generate additional flow rates by adding additional capillaries (1) with selected fluid restrictions. For example, 5 capillaries would generate a total of 32 different flow rates, calculated at 2 to the fifth power. Or if each capillary was incremented by 5ml/hr (5, 10, 15, 20) the user could have variable flows from 5ml/hr to 75ml/hr in 5ml/hr increments.

While the variable rate flow control for practicing the within inventive method, as well as said method herein shown and disclosed in detail is fully capable of attaining the objects and providing the advantages hereinbefore stated, it is to be understood that it is merely illustrative of the presently preferred embodiment of the invention and that no limitations are intended to the detail of construction or design herein shown other than as defined in the appended claims.